II. Statements & Certifications (continued)

B. 510(k) Summary

NOV 5 2012

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K123182

The purpose of this 510(k) submission is to update the package insert of the currently cleared OSOM® Influenza A&B test (K092633) to include additional analytical reactivity information.

1. Sponsor/Applicant Name and Address:

Company Name:	Sekisui Diagnostics, LLC
Address:	6659 Top Gun Street San Diego, CA 92121
Telephone:	(858) 777-2633
Fax:	(858) 452-3258
Contact Person:	Mark Stavro Director, Regulatory Affairs
Date Summary Prepared:	October 5, 2012

2. Device Name and Classification:

Trade Name:	OSOM® Influenza A&B Test
Classification of Device:	21CFR 866.3330, Influenza virus serological reagents Product Code: GNX, antigens, CF, influenza Virus A, B, C
Classification Panel:	Microbiology
Classification:	Class I

3. Predicate Device:

OSOM® Influenza A&B Test (K092633, cleared September 25, 2009)

4. Device Description:

The OSOM® Influenza A&B Test consists of a test stick that separately detects influenza A and B. The test procedure requires the solubilization of the nucleoproteins from a swab by mixing the swab in Extraction Buffer. The test stick is then placed in the sample mixture, which then migrates along the membrane surface. If influenza A and/or B viral antigens are present in the sample, it will form a complex with mouse monoclonal IgG antibodies to Influenza A and/or B nucleoproteins conjugated to colloidal gold. The complex will then be bound by another mouse anti-influenza A and/or B antibody coated on the nitrocellulose membrane. A pink to purple control line must appear in the control region of the stick for results to be valid. The appearance of a second and possibly a third light pink to purple line will appear in the test line region indicating an A, B or A and B positive result.

5. Device Intended Use

The OSOM® Influenza A&B Test is an in vitro diagnostic immunochromatographic assay intended for the qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections. This test is not intended for the detection of influenza C viruses. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

6. Comparison to Predicate Device

The OSOM® Influenza A&B Test is the same device as the predicate OSOM® Influenza A&B Test, and no design or procedural changes have been made. The table below lists the characteristics of the OSOM® Influenza A&B Test (new Performance Characteristic) and the predicate OSOM® Influenza A&B Test (original Performance Characteristic).

Device Characteristics	**New Device: OSOM® Influenza A&B Test**	**Predicate Device: OSOM® Influenza A&B Test (K092633)**
Intended Use	The OSOM® Influenza A&B Test is an in- vitro diagnostic immunochromatographic assay intended for the qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections. This test is not intended for the detection of	The OSOM® Influenza A&B Test is an in- vitro diagnostic immunochromatographic assay intended for the qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in symptomatic patients. It is intended to aid in the rapid differential diagnosis of influenza A and/or B viral infections. This test is not intended for the detection of

	influenza C viruses. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.	influenza C viruses. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.
Sample type	Nasal Swab	Nasal Swab
Analytical principle	Lateral flow immunochromotographic assay	Lateral flow immunochromotographic assay
Antibody	Mouse monoclonals	Mouse monoclonals
Extraction buffer volume	300uL	300uL
Read time for results	10 minutes	10 minutes
Objective Test Line	Colloidal gold	Colloidal gold
Internal Control	Pink to purple line	Pink to purple line
Control samples supplied (as prepared swabs)	Positive Influenza A Positive Influenza B (Positive A acts as negative B; Positive B acts as negative A)	Positive Influenza A Positive Influenza B (Positive A acts as negative B; Positive B acts as negative A)

Based on analytical reactivity data presented in the pre-market notification, the OSOM® Influenza A&B Test package insert has been updated to include additional analytical reactivity information for the following H3N2v Influenza A strains:

A/WEST VIRGINIA/06/2011
A/PENNSYLVANIA/14/2010
A/MINNESOTA/11/2010
A/KANSAS/13/2009
A/INDIANA/08/2011
A/INDIANA/10/2011

Results from testing demonstrated that the OSOM® Influenza A&B Test reacts with the cultured strains of the H3N2v Influenza A virus strains listed above, and all are detectable.

The Analytical Reactivity table for the influenza A strains, which is currently included in the predicate OSOM® Influenza A&B Test package insert labeling, will be updated as indicated in the table on the following page.

Current Analytical Reactivity Table for Influenza A Strains

Influenza A Strains:	Sub-type	Estimated ELISA $TCID_{50}$/mL
Beijing/262/95	H1N1	8.25E+07
Brazil/11/78	H1N1	NA
Chile/1/83	H1N1	NA
New Jersey/8/76	H1N1	2.78E+08
Taiwan/1/86	H1N1	3.47E+07
Guizhou/54/89	H3N2	7.54E+07
OMS/5389/88	H3N2	NA
Beijing/32/92	H3N2	3.97E+06
England/427/88	H3N2	4.73E+07
Johannesburg/33/94	H3N2	1.61E+07
Leningrad/360/86	H3N2	2.50E+06
Mississippi/1/85	H3N2	NA
Philippines/2/82	H3N2	9.75E+07
Shangdong/9/93	H3N2	1.67E+08
Shanghai/16/89	H3N2	3.49E+08
Shanghai/24/90	H3N2	NA
Sichuan/2/87	H3N2	NA
Kitakyushyu/159/93	H3N2	3.19E+08
Akita/1/94	H3N2	2.90E+08
Beijing/262/95	H1N1	1.71E+08
Yamagata/32/89	H1N1	7.28E+07
New Caledonia/20/99	H1N1	6.86E+07
Panama/2007/99	H3N2	1.40E+08
Wyoming/03/03	H3N2	7.40E+06
Fujian/411/02	H3N2	6.12E+07
*Mexico/4108/2009***	H1N1	7.91E+06 EID_{50}/mL*

* The estimated detectable limit for the Mexico/4108/2009 strain was based on the EID_{50}/mL stock concentration value provided by the CDC.

**Although this test has been shown to detect the 2009 H1N1 virus cultured from a positive human respiratory specimen, the performance characteristics of this device with clinical specimens that are positive for the 2009 H1N1 influenza virus have not been established. The OSOM Influenza A&B test can distinguish between influenza A and B viruses, but it can not differentiate influenza subtypes.

Updated Analytical Reactivity Table for Influenza A Strains

Influenza A Strains	Sub-type	Estimated ELISA $TCID_{50}$/mL
Beijing/262/95	H1N1	8.25E+07
Brazil/11/78	H1N1	NA
Chile/1/83	H1N1	NA
New Jersey/8/76	H1N1	2.78E+08
Taiwan/1/86	H1N1	3.47E+07
Guizhou/54/89	H3N2	7.54E+07
OMS/5389/88	H3N2	NA
Beijing/32/92	H3N2	3.97E+06
England/427/88	H3N2	4.73E+07
Johannesburg/33/94	H3N2	1.61E+07
Leningrad/360/86	H3N2	2.50E+06
Mississippi/1/85	H3N2	NA
Philippines/2/82	H3N2	9.75E+07
Shangdong/9/93	H3N2	1.67E+08
Shanghai/16/89	H3N2	3.49E+08
Shanghai/24/90	H3N2	NA
Sichuan/2/87	H3N2	NA
Kitakyushyu/159/93	H3N2	3.19E+08
Akita/1/94	H3N2	2.90E+08
Beijing/262/95	H1N1	1.71E+08
Yamagata/32/89	H1N1	7.28E+07
New Caledonia/20/99	H1N1	6.86E+07
Panama/2007/99	H3N2	1.40E+08
Wyoming/03/03	H3N2	7.40E+06
Fujian/411/02	H3N2	6.12E+07
*Mexico/4108/2009***	H1N1	7.91E+06 EID_{50}/mL*
*West Virginia/06/2011***	H3N2v	1.0E+05*
*Pennsylvania/14/2010***	H3N2v	1.0E+08 EID_{50}/mL*
*Minnesota/11/2010***	H3N2v	1.0E+08 EID_{50}/mL*
*Kansas/13/2009***	H3N2v	1.0E+05*
*Indiana/08/2011***	H3N2v	1.0E+06 EID_{50}/mL*
*Indiana/10/2011***	H3N2v	1.00E+09*

* The estimated detectable limit for the Mexico/4108/2009 strain and these H3N2v strains were based on the EID_{50}/mL or $TCID_{50}$/mL stock concentration value provided by the CDC.

**Although this test has been shown to detect these 2009 H1N1 and H3N2v viruses cultured from positive human respiratory specimens, the performance characteristics of this device with clinical specimens that are positive for these 2009 H1N1 and H3N2v influenza viruses have not been established. The OSOM Influenza A&B test can distinguish between influenza A and B viruses, but it can not differentiate influenza subtypes.

A copy of the updated, proposed package insert for the OSOM® Influenza A&B Test is included in **Attachment 1**. Please refer to **Attachment 2** for a copy of the Predicate OSOM® Influenza A&B Test package insert. In addition, please refer to **Attachment 4** for two additional copies of the proposed package insert for the OSOM® Influenza A&B Test for CLIA Categorization: Moderate Complexity.

7. Conclusion

The information presented in this pre-market notification demonstrates that the OSOM® Influenza A&B Test reacts with the following six additional H3N2v strains:

A/WEST VIRGINIA/06/2011
A/PENNSYLVANIA/14/2010
A/MINNESOTA/11/2010
A/KANSAS/13/2009
A/INDIANA/08/2011
A/INDIANA/10/2011

Although this test has been shown to detect these H3N2v strains in culture isolates, the performance characteristics of this device with clinical specimens that are positive for these H3N2v strains have not been established. The OSOM® Influenza A&B Test can distinguish between influenza A and B viruses, but it can not differentiate influenza subtypes.

The OSOM® Influenza A&B Test is substantially equivalent to the predicate OSOM® Influenza A&B Test, which is cleared by the FDA (K092633) for in vitro diagnostic use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Sekisui Diagnostics, LLC
C/O Mark Stavro
Director, Regulatory Affairs
6659 Top Gun St
San Diego, California, 92121

NOV 5 2012

Re: K123182
Trade/Device Name: OSOM® Influenza A&B Test
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza virus serological reagents
Regulatory Class: Class I
Product Code: GNX
Dated: October 5th, 2012
Received: October 10th, 2012

Dear Mr. Stavro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

II. Statements & Certifications

A. Statement of Intended Use

510(k) Number (if known): K123182

Device Name: OSOM® Influenza A&B Test

Indications for Use: The OSOM® Influenza A&B Test is an in vitro diagnostic Immunochromatographic assay intended for the qualitative detection of influenza A and influenza B viral nucleoprotein antigens from nasal swab specimens in symptomatic patients. It is intended to aid in the rapid differential diagnosis of Influenza A and/or B viral infections.

This test is not intended for the detection of influenza C viruses. A negative test is presumptive and it is recommended these results be confirmed by cell culture. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801.109) (per 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Tamara Feldblyum

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

K123182